



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 23, 2018

John D. Abbott, Ph.D., CPH  
NA Regulatory Team Leader  
Syngenta Crop Protection, LLC.  
P.O. Box 18300  
Greensboro, NC 27419-8300

Dear Dr. Abbott:

This letter is in response to your letter dated July 17, 2018, concerning a situation where an unforeseen foreign production site closure has led to disruptions in availability of 1,2-benzisothiazolin-3-one (BIT) (CAS Reg. No. 2634-33-5). In that letter, you requested that the Agency approve a self-certification process, in lieu of submission of Confidential Statement of Formulation (CSF) for each of the impacted end-use products.

The Agency has considered your request and determined that there is sufficient flexibility in our current regulatory scheme to allow for a temporary process to address the issue during this period of supply chain uncertainty. We are providing the regulatory framework, as well as details of that process, in this letter.

PR Notice 98-10, Section III.B., allows registrants to change the source of inert ingredients in a formulation from the current source to a new source by notification, where EPA has required the identification of a source, as EPA regularly does on the CSF. BIT, when acting as a preservative in a pesticide product but not providing the intended pesticidal effect of that pesticide product, is considered as an inert or other ingredient in that product. Provided, the new source of BIT is a registered source included in the list below, the Agency has determined that notification for several products at one time without the need to provide updated CSFs temporarily provides sufficient information to satisfy the Agency's regulatory needs. Therefore, given the temporary nature of the BIT supply disruption, the Agency has determined that for a period not to exceed 24 months, we will allow registrants of pesticide products containing BIT as an inert or other ingredient to use a streamlined self-certification process to notify changes in BIT supplier for end-use products. The details of the process are outlined further in this letter.

Understanding the urgency of the issue, and the need to minimize resource expenditures to both registrants and the Agency, the following streamlined self-certification process is proposed. Provided the change in source of BIT is to a registered product as listed below, in lieu of submission of amended CSFs for all impacted products, EPA will allow notification of the source

change to be submitted in the form of a single letter which covers all the impacted products. The notification should include the following self-certification statement:

*"The source of BIT in EPA Registration No. [ xxx-xx, etc.] is solely limited to one or more of the products listed in the Agency letter dated 8/23/18 and that no other changes to the product formulation other than the use of an acceptable alternative source of BIT has been made. This self-certification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this self-certification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement actions and penalties under section 12 and 14 of FIFRA."*

This list below details the acceptable alternate registered sources of BIT.

<b>Tradename</b>	<b>Supplier Name</b>	<b>% BIT</b>	<b>EPA Reg. No.</b>
Acticide B20	Thor Specialties, Inc. Shelton, CT	20%	67071-22
Acticide BW20	Thor Specialties, Inc. Shelton, CT	20%	67071-23
Proxel BD20	Arch Chemicals Alpharetta, GA	19.30%	1258-1260
Proxel GXL	Arch Chemicals Alpharetta, GA	19.13%	1258-1255
TROYGUARD B20F (also Mergal BIT20)	Troy Corporation Florham Park, NJ	19.18%	5383-144
TROYGUARD B20G (Mergal BIT20X)	Troy Corporation Florham Park, NJ	19.18%	5383-121
Mergal BIT20W	Troy Corporation Florham Park, NJ	19.18%	5383-144

At the end of this 24-month period, unless evidence is presented that there continues to be market instability, the Agency will require the submission of new or amended CSFs for any product for which the source of BIT has changed from what is listed in the current CSF. The

Agency would expect that such submissions would be made within 90 days of August 23, 2020, or upon identification of stable source(s), whichever occurs earlier.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Goodis", with a stylized flourish extending to the right.

Michael Goodis, Director  
Registration Division  
Office of Pesticide Programs